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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CLARK, GREGORY D

ART UNIT	PAPER NUMBER
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1794

MAIL DATE	DELIVERY MODE
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03/12/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,923	Applicant(s) BUREAU ET AL.	
	Examiner GREGORY CLARK	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-22, 24 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23, 25-27 and 29-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/25/2010 has been entered.

The examiner acknowledges receiving the applicant's amended claims dated 10/01/2009. Claims: 23, 24, 25-27 and 30; 29 previously presented; 1-22, 24 and 28. cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 1. Claims 23, 25-26, and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bertrand (WO 2002/098926) in view Stirling (Advanced Materials, 2000, 12, No. 16, p. 1161-1171)**

2. **Regarding Claim 23**, Bertrand teaches electrografting a strong adherent polymer coating on an electrically conductive surface comprising an electrochemical grafting at the surface of an active monomer (comprising a reactive functional group for attachment of a molecule having at least one complementary reactive group) (Page 5, lines 8-11). Bertrand further teaches electrografted coatings of polymers such as polyhydroxyethylacrylate (contains hydroxyl protic groups) can be deposited on the conducting substrates with a strong adhesion and an increased and tunable thickness (controllable thickness) (page 8, lines 18-20).

Bertrand does not teach electrografting resulting in 90% of the total functional groups being accessible of the functional groups and the density of accessible functional groups of interest is between $10^4/\text{micron}^2$ and $10^{10}/\text{micron}^2$.

Stirling discloses that for a functionalized metal surface composed of an organic layer with a pendant functional group for the immobilization of a biomaterial, steric crowding can decrease the amount of reaction between the functional groups and the biomaterial. Stirling specifically discloses that the reaction rate is substantially diminished with steric crowding around the reaction center (page 1169).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have carried out an electrografting process by adjusting the level of accessible of the functional groups and the density of the functional groups to account for the expected steric constraints (crowding of the functional groups limit reactivity) which would have included the claimed ranges, absent unexpected results.

3. **Regarding Claim 25**, Bertrand teaches grafted activated vinyl monomers (organic precursor) can undergo controlled or uncontrolled ring opening polymerization (referred to by the applicant as molecules that are cleavable by nucleophilic attack) (page 8, lines 23-31).

4. **Regarding Claim 26**, Bertrand discloses electro-reactive species in the form of acrylates and methacrylates containing an anchoring group (labeled as the X group in diagram page 5) that can be electrografted to conductive surfaces (page 5, lines 7-31). Bertrand mentions glycidyl methacrylate (page 9, line 9) and polyhydroxyethylacrylate (contains hydroxyl protic groups) (page 8, lines 18-20). As some of the monomers used in electrografting.

5. **Regarding Claim 29**, Bertrand teaches electrografting reactions on steel, stainless steel, Inco316L, tantalum, titanium, nitinol carbon, ITO glass, transition metal (Fe, Ni, Cu, Au, and Ag), metal doped polymers (page 6, lines 30-32).

6. **Regarding Claims 30**, Bertrand teaches electrografting acrylates or methacrylates (organic precursors) containing an anchoring group for attachment of a molecule having at least one complementary reactive group (page 5, lines 20-26).

Bertrand further teaches electrografted coatings of polymers such as polyhydroxyethylacrylate (contains hydroxyl protic groups) can be deposited on the (page 8, lines 18-20).

The process allows the grafting onto the initial coating (adhesion primer) by compounds like functional polymers such as, protein, peptide, oligonucleotide (defined as DNA chips, page 4, line 28), dyes, drugs, and anti-bacterian compounds (page 6, lines 9-11).

Bertrand also mentions the use of monomeric species which do not have reactive functional groups such as polystyrene (page 8, line 18) and (page 22, lines 12-28). Bertrand fails to mention a formulation composed of a mixture of monomers with and without a reactive functional group.

Stirling discloses that for a functionalized metal surface composed of an organic layer with a pendant functional group for the immobilization of a biomaterial, steric crowding can decrease the amount of reaction between the functional groups and the biomaterial. Stirling specifically discloses that the reaction rate is substantially diminished with steric crowding around the reaction center (page 1169).

The use of monomers that do not have reactive functional groups is viewed as an obvious means decrease the degree of steric crowding. Functionalized substrates with an excessive amount of surface coverage by species with reactive functional groups would be expected to result in steric crowding of the reactive groups leading to a decrease in accessibility with respect to the subsequent grafting of vicinal bio-

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molecules. Balancing the monomer ratio of reactive versus non-reactive groups would be an obvious means to control steric crowding.

In essence, it would have been obvious to a person of ordinary skill in the art at the time of the invention to have formulated a mixture of monomers with and without reactive groups to control steric crowding to ensure that a suitable percentage of reactive groups were accessible during the subsequent grafting of vicinal bio-molecules.

7. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bertrand (WO 2002/098926) in view of Stirling (Advanced Materials, 2000, 12, No. 16, p. 1161-1171) and further in view of Fukuchi (US 4,691, 045).

8. Regarding Claim 27, Bertrand teaches the use of lactones and lactides such as (ε-caprolactone), and functional caprolactones such as γ-bromo- ε-caprolactone, or lactide such as D, L-Lactide or any other polymerizable cyclic monomer such as cyclic anhydride (page 9, lines 1-4).

It is understood in the art that materials such as lactones are susceptible to nucleophilic at the electronegative carbonyl group.

Bertrand fails to mention substituted ethylene oxides

Fukuchi discloses that hydroxyl containing methacrylate materials react with oxygen containing cyclic compounds (column 18, lines 40-43) such as epoxy compounds and lactones (column 18, lines 67-68). The epoxy compounds include alkylene oxides such as propylene oxide (a substituted ethylene oxide) (column 19,

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lines 8-9). The hydroxyl containing methacrylate material that Fukuchi discloses polyhydroxyethylacrylate) (column 18, lines 40-43) is the same as Bertrand (page 8, lines 18-20).

The examiner notes that applicant includes hydroxylethyl metacrylate as an example of formula I (vinyl monomer) which is used to react with formula II (material cleavable by nucleophilic attack).

Fukuchi shows that the nucleophilic attack of oxygen containing cyclic compounds such as lactones and propylene oxides can be carried out by the same nucleophilic agent, namely a hydroxyl containing methacrylate material. As both oxygen containing cyclic compounds are cleavable by a reaction with the same hydroxylethyl methacrylate materials, these cyclic materials would be considered as functional equivalents.

It would have been obvious to a person of ordinary skill in the art at the time of the invention to have used propylene oxide (a substituted ethylene oxide) in place of the lactones material since Fukuchi discloses that these oxygen containing cyclic materials are susceptible to nucleophilic from hydroxylethyl metacrylate materials and would thus be considered as functional equivalents, absent unexpected results.

Response to Arguments

The applicant argues that the prior art does not show vinyl or cyclic monomers bearing protic groups which renders the prior as limited to indirect immobilization.

Although Bertrand discloses the use of some aprotic monomers, Bertrand's disclosure is not limited to aprotic monomers. Bertrand also discloses electrografted coatings of polymers such as polyhydroxyethylacrylate (contains hydroxyl (protic) groups) can be deposited on the conducting substrates with a strong adhesion and an increased and tunable thickness (controllable thickness) (page 8, lines 18-20).

With respect to accessible functional groups and the density of the functional groups of interest, Stirling clearly discloses that steric crowding play a critical role in decreasing functional groups reactivity.

It would have been obvious in the electrografting process to adjust the level of the "functional group containing species" which would affect the density of such species in order to account for the expected steric constraints (crowding of the functional groups limit reactivity) to produce the desired percentage of functional group accessibility and the ultimate density of the reactive groups.

As the prior art teaches the grafting of bio-molecules that are the same or in similar categories to those claimed by the applicant, it would have been obvious to one of ordinary skill in the art at the time of the invention to have conducted routine experiments to determine the appropriate level of reactive group containing monomer to ensure a suitable level of grafting which would have included the claimed accessibility and density ranges.

Sequence Rule Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons. Sequences appear at page 38, line 15, page 42, lines 14 and 20 and a paper copy of a sequence listing was submitted December 23, 2004 but no computer readable form has been submitted.

Help with compliance with the sequence rules is available from Robert Wax, SPE of Art Unit 1615 whose number is (571) 272-0623.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY CLARK whose telephone number is (571)270-7087. The examiner can normally be reached on M-Th 7:00 AM to 5 PM Alternating Fri 7:30 AM to 4 PM and Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. Lawrence Tarazano/
Supervisory Patent Examiner, Art Unit 1794

/GREGORY CLARK/GDC/
Examiner, Art Unit 1794

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